

### REMARKS

Entry of this Amendment is proper under 37 C.F.R. § 1.116, because the Amendment places the application in condition for allowance for the reasons discussed herein; does not raise any new issue requiring further search and/or consideration because the amendments amplify issues previously discussed throughout prosecution, and places the application in better form for an appeal should an appeal be necessary.

As set forth in the Office Action, claims 17, 20 and 24-36 are currently pending. Claims 17, 26, and 32 are amended herein. Claim 17 is amended herein to clarify that a hydroxylation takes place at position 17. Claims 17 and 32 are amended to recite that the modification of the yeast cells resulting in a lack of acetyl coenzyme A-pregnenolone acetyltransferase (APAT) activity is caused by the inactivation of the *Saccharomyces cerevisiae* atf2 gene. Claim 26 is amended to recite the steroid precursor hydroxylation at position 17. Basis for these amendments may be found in the specification and claims as-filed, especially at page 9, lines 26-27 and claims 24, 29 and 36 as-filed.

Claims 24, 29 and 36 are canceled herein as redundant in light of the amendments to the claims. Applicants reserve the right to file at least one continuation or divisional application directed to any subject matter canceled by way of the present Amendment.

### **Information Disclosure Statement**

Applicants note with appreciation that the Information Disclosure Statement of April 26, 2004, has been considered by the Examiner.

***Objection to claim 17***

Claim 17 stands objected to for the recitation of "DHEA". Claim 17 is amended herein to recite the full term "dehydroepiandrosterone", as requested by the Examiner. Thus, this objection is obviated.

***Rejection under 35 U.S.C. § 112, second paragraph***

Claim 26 stands rejected under 35 U.S.C. § 112, second paragraph, as it is purportedly unclear how the 17 $\beta$ -hydroxysteroid dehydrogenase activity takes place at position 17. As suggested by the Examiner, claim 26 is amended herein to recite the production of a steroid precursor hydroxylated at position 17. Applicants submit this rejection is obviated.

***Rejection under 35 U.S.C. § 112, first paragraph***

Claims 17-30, 32 and 34-46 stand rejected under 35 U.S.C. § 112, first paragraph, as purportedly lacking written description. The Office asserts that the specification only discloses a few species of genes, steroid precursors, yeast strains, and modifications lacks written description for the claims as currently set forth.

Without acquiescing in the rejection and in order to expedite prosecution, independent claims 17 and 32 are amended herein to recite that the yeast cells are *Saccharomyces cerevisiae* cells, and that the modification of the yeast cells resulting in a lack of acetyl coenzyme A-pregnenolone acetyltransferase (APAT) activity is caused by the inactivation of the *Saccharomyces cerevisiae* atf2 gene. As the Office

has acknowledged that this subject matter is supported by the specification,  
Applicants submit that this rejection should be withdrawn.

The Office states further states that while the claimed invention requires the use of the rat *Cyp7b* gene, the specification fails to recite the structural elements associated with the rat *Cyp7b* gene. Applicants submit that the structure of the rat *Cyp7b* gene would be well known by those of skill in the art. First, Applicants turn to page 4, lines 26-35 of the specification, which state that the *Cyp7b* gene is known and has been described in Stapleton et al. (1995, *J. Biol. Chem.* 270:29739-29745), and the sequence of which is set forth in WO 96/12820, and accessible from Institute for Fermentation Osaka under the accession code IFO 2031. Thus, Applicants submit that the sequence of the *Cyp7b* gene is supported by what is known to the skilled artisan.

Claims 17-30, 32 and 34-36 also stand rejected under 35 U.S.C. § 112, first paragraph, as purportedly not enabled. As discussed above, independent claims 17 and 32 are amended herein to recite that the yeast cells are *Saccharomyces cerevisiae* cells, and that the modification of the yeast cells resulting in a lack of acetyl coenzyme A-pregnenolone acetyltransferase (APAT) activity is caused by the inactivation of the *Saccharomyces cerevisiae* atf2 gene. As the Office has noted that this subject matter is enabled by the specification, Applicants request that this rejection be withdrawn.

In light of the above, Applicants respectfully submit that the presently claimed invention fully complies with both the written description and enablement requirements of 35 U.S.C. § 112, first paragraph. Accordingly, withdrawal of this rejection is respectfully requested.

**CONCLUSION**

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

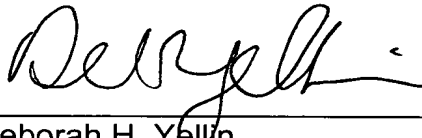
In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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By: \_\_\_\_\_

  
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